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10/050,238	01/16/2002	Michael Paul Aronson	J6699/1(C)	6809
201	7590	02/04/2004	EXAMINER	
UNILEVER PATENT DEPARTMENT 45 RIVER ROAD EDGEWATER, NJ 07020			JIANG, SHAOJIA A	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 02/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/050,238

Applicant(s)

ARONSON ET AL.

Examiner

Shaojia A Jiang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 1 and 4-18 is/are pending in the application.
- 4a) Of the above claim(s) 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 4-7, and 9-13 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

This Office Action is a response to Applicant's amendment and response filed on November 14, 2003 wherein claims 2-3 and 8 are amended; claims 1, 4-7, and 8-13 have been amended and claims 14-18 are newly submitted. Currently, claims 1, 4-7, and 9-18 are pending in this application.

It is noted that the newly claims 14-18 are drawn to a composition herein that is independent and distinct from the invention originally claimed, which is entirely directed to a process for making a wet-skin treatment composition herein.

According to MPEP § 819, the general policy of the Office is not to permit the applicant to shift to claiming another invention after an election is once made and/or an action given on the merits.

In the instant case, the original invention (claims 1-13) is drawn to a process for making a wet-skin treatment composition herein, whereas the invention of newly submitted claims 14-18 is drawn to a composition. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the composition in the new claims 14-18 can be made by another and materially different process.

Thus, the original invention and the newly claimed invention are seen to be separate and distinct inventions. Note that a reference to the composition herein would

Art Unit: 1617

not necessarily be a reference to the method of making or the process for making under 35 USC 103. The composition and method of making herein have separate consideration as to patentability.

Therefore, claims 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1, 4-7, and 9-13 as amended now are examined on the merits herein.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4-7, and 9-13 are rejected under 35 U.S.C. 112, first paragraph, for scope of enablement because the specification, while being enabling for the particular compounds or agents for a inorganic, organic, or polymeric stabilizer, the particular skin oils, the particular structurants, the particular auxiliary benefit agents, disclosed in the specification (see page 7-17 of the specification herein) in composition herein to be made by the claimed process, does not reasonably provide enablement for any compounds for each kind having functional properties recited in the claims herein.

These recitations, "a inorganic, organic, or polymeric stabilizer", "a skin compatible oil", "a structurant", and "an auxiliary benefit agent", are seen to be merely functional language.

Art Unit: 1617

The instant specification fails to provide information that would allow the skilled artisan to fully practice the instant invention without **undue experimentation**. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApl 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

The nature of the invention: The instant invention pertains to a process for making a cosmetic composition.

The relative skill of those in the art: The relative skill of those in the art is high.

The breadth of the claims: The instant claims are deemed very broad since the broadest claim (i.e., claim 1) reads on any compounds for each kind having functional properties recited in the claims herein.

The amount of direction or guidance presented:

Functional language at the point of novelty, as herein employed by Applicants, is admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC, 1997) at 1406: stating this usage does "little more than outline goal appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". The CAFC further clearly states that "[A] written description of an invention involving a

Art Unit: 1617

chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials” at 1405(emphasis added), and that “It does not define any structural features commonly possessed by members of the genus that distinguish from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus..” at 1406 (emphases added).

In the instant case “a inorganic, organic, or polymeric stabilizer”, “a skin compatible oil”, “a structurant”, and “an auxiliary benefit agent”, recited in the instant claims are purely functional distinction. Hence, these functional recitations read on any compounds that might have the recited functions. However, the specification merely provides those particular compounds for each kind of functional compounds for the composition to be made by the claimed process (see page 12 of the specification).

Thus, Applicants functional language at the points of novelty fails to meet the requirements set forth under 35 U.S.C. 112, first paragraph. Claims employing functional language at the exact point of novelty, such as Applicants’, neither provide those elements required to practice the inventions, nor “inform the public during the life of the patent of the limited of monopoly asserted” (*General Electric Company v. Wabash Appliance Corporation et al.* 37 USPQ at 468 (US Supreme Court 1938)).

The predictability or unpredictability: the instant claimed invention is highly *unpredictable* as discussed below:

Art Unit: 1617

In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art cannot fully described genus, visualize or recognize the identity of the members of the genus, by structure, formula, or chemical name, of the claimed subject matter, as discussed above in *University of California v. Eli Lilly and Co.* Hence, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would be unable to fully predict possible physiological activities of any compounds having claimed functional properties in the cosmetic compositions herein to be applied to the skin of the host, a topical administration.

Moreover, one of skill in the art would recognize that it is highly unpredictable in regard to therapeutic effects, and side effects, especially serious toxicity that may be generated by drug-drug interactions when and/or after applying to skin, a topical administration of the **combination** of any compounds represented by “a inorganic, organic, or polymeric stabilizer”, “a skin compatible oil”, “a structurant”, and “an auxiliary benefit agent”, which may encompass more than a thousand compounds. See text book “Goodman & Gilman’s The Pharmacological Basis of Therapeutics” regarding possible drug-drug interactions (9<sup>th</sup> ed, 1996) page 51 in particular. This book teaches that “The frequency of significant beneficial or adverse drug interactions is unknown” (see the bottom of the left column of page 51) and that “Recognition of beneficial effects and recognition of and prevention of adverse drug interactions require a thorough knowledge of the intended and possible effects of drugs that are prescribed” and that “The most important adverse drug-drug interactions occur with drugs that have serious toxicity and a low therapeutic index, such that relatively small changes in drug level can

Art Unit: 1617

have significant adverse consequences" (see the right column of page 51) (emphases added). In the instant case, in the absence of fully recognizing the identity of the members genus herein, one of skill in the art would not be able to fully predict possible adverse drug-drug interactions occurring with many combinations of any compounds having claimed functional properties in the pharmaceutical or cosmetic compositions herein to be administered to a host. Thus, the teachings of the book clearly support that the instant claimed invention is highly unpredictable.

The presence or absence of working examples and the quantity of experimentation necessary:

As discussed above, only those particular compound for each kind of functional compounds employed in the composition herein is disclosed in the specification. Moreover, it is noted that the specification merely provide those particular compositions comprising particular compounds in working examples (see page 38-61). Thus, the evidence in the examples is not commensurate in scope with the claimed invention and does not demonstrate criticality of a claimed range of the ingredients in the claimed composition to be made by the claimed process. See MPEP § 716.02(d).

Thus, the specification fails to provide sufficient support of the broad use of any compounds having those functions recited in the instant claims. As a result, necessitating one of skill to perform an exhaustive search for the embodiments of any compounds having those functions recited in the instant claims suitable to practice the claimed invention.



Art Unit: 1617

*Genentech*, 108 F.3d at 1366, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable".

Therefore, in view of the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test all compounds encompassed in the instant claims and their combinations employed in the claimed compositions to be administered topically to the skin of a host, with no assurance of success.

Applicant's remarks filed on November 14, 2003 with respect to this rejection made under 35 U.S.C. 112, first paragraph, for lack of scope of enablement of record in the previous Office Action August 13, 2003 have been fully considered but are not deemed persuasive. These remarks are believed to be adequately addressed by the obvious rejection presented above.

Additionally, as noted in MPEP 2111, during patent examination, claims are given their broadest reasonable interpretation. It is proper to use the specification to interpret what the applicant meant by a word or phrase recited in the claim, However, it is not proper to read limitations appearing in the specification into the claim when these limitations are not recited in the claim. See *In re Paulsen*, 30 F.3d 1475, 1480, 31 USPQ2d 1671, 1674 (Fed. Cir. 1994) for example.

Art Unit: 1617

In the instant case, as discussed in the previous Office Action and above, the instant claims (i.e., claim 1) read on **any** inorganic, organic, or polymeric stabilizers, **any** skin compatible oils, **any** structurants, and **any** auxiliary benefit agents. The instant claims clearly lack of scope of enablement for any inorganic, organic, or polymeric stabilizers, any skin compatible oils, any structurants, and any auxiliary benefit agents recited in claim 1 without **undue experimentation**, based on the Wands factors, the case *University of California v. Eli Lilly and Co.* (CAFC, 1997) and *In re Fisher* (CCPA 1970).

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-7, and 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsaor et al. (US 5,759,969, of record).

Tsaor et al. discloses the process for making a cosmetic composition therein for applying to skin comprising the particular instant ingredients, i.e., water, particular oil such as silicone oil, sunflower seed oil, and soy bean oil (see col.8 lines 34-35 and 60), particular dispersion stabilizers including esters therein (see col.8 lines 53-59) and fatty acids (see col.8 lines 47-49), particular structurants such as hyddrogel (see col.5-6 for example) and particular auxiliary benefit agents herein such as (see col.8 line 8 to col.

Art Unit: 1617

9 line 17, and col.12 lines 37-40). See also abstract, col.12 lines 37-40; for particular compositions made therein see Examples 1-16 at col. 13-25; and claim 1.

Tsaur et al. also discloses the inherent properties of the compositions therein, i.e., the particular viscosity higher than 300 poise, preferred higher 1000, within the instant claimed range(see col.3 lines 4-6 and col.12 lines 34-35); having particle size greater than 25, 100, or 200 microns (see col.3 lines 4-6 and 27-30).

Moreover, it has been well settled that recitation of an inherent property of a composition, will not further limit claims drawn to a composition.

Applicant is further requested to note that it is well settled that "intended use" of a composition or product, e.g., "a wet-skin treatment" in claim 1, will not further limit claims drawn to a composition or product. See, e.g., *Ex parte Masham*, 2 USPQ2d 1647 (1987) and *In re Hack* 114, USPQ 161.

Applicant's remarks filed on November 14, 2003 with respect to this rejection of made under 35 U.S.C. 102(b) as being anticipated by Tsaur et al. of record stated in the Office Action dated August 13, 2003 have been fully considered but they are not deemed persuasive to render the claimed invention patentable over the prior art as further discussed below.

Applicant asserts that:

"the processes of Tsaur et al and of the invention are fundamentally different and accordingly result in fundamentally different compositions. Specifically, Tsaur et al. is directed to a process for preparing aqueous compositions containing so called hydrogel particles (formed by two different polymers) wherein skin benefit agent is entrapped

Art Unit: 1617

within the padicles. That is, the hydrogel particles "trap" water insoluble benefit agents within a network formed by these two polymers. The polymer network so formed (i.e. hydrogei) is able to disintegrate smoothly when rubbed on a substrate such as skin thereby releasing the entrapped benefit agent (Column 2, line 64 to Column 3, line 1)"

However, the instant claims read on hydrogel particles and hydrogel network which is also 3-dimension. Moreover, the instant steps recited in the claims are not limited to any specific order and sequence.

Thus, the disclosure of Tsaur et al. anticipates claims 1, 4-7, and 9-13.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4-7, and 9-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,395,690, for the same reasons of record in the previous Office Action August 13, 2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a process for making a personal cleansing composition comprising the instant ingredients and having the instant inherent properties. Thus, the instant claims 1, 4-7, and 9-13 are seen to be anticipated by the claims 1-5 of U.S. Patent No. 6,395,690.

Claims 1, 4-7, and 9-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,218,348, for the same reasons of record in the previous Office Action August 13, 2003.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patent is drawn to a process for making a bar composition comprising the instant ingredients and having the instant inherent properties. Thus, the instant claims 1, 4-7, and 9-13 are seen to be anticipated by the claims 1-17 of U.S. Patent No. 6,218,348.

It is noted in Applicant's response regarding these obviousness-type double patenting rejections that "In this regard, applicants submit a Terminal Disclaimer terminally disclaiming that portion of any claims which would expire beyond the expiration date of claims pending in US Patent no. 6,395,690 or in US Patent no. 6,218,348". However, such a Terminal Disclaimer is not found in the File.

In view of the rejections to the pending claims set forth above, no claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.  
Patent Examiner, AU 1617  
January 29, 2004

  
**SREENI PADMANABHAN**  
SUPERVISORY PATENT EXAMINER

2/2/04